

PATENT COOPERATION TREATY
PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

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Applicant's or agent's file reference 1149WOORD01	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/EP2004/050493	International filing date (day/month/year) 08/04/2004	(Earliest) Priority Date (day/month/year) 11/04/2003
Applicant ALTANA PHARMA AG		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. Certain claims were found unsearchable (See Box II).

3. Unity of invention is lacking (see Box III).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

ORAL PHARMACEUTICAL PREPARATION COMPRISING A PROTON PUMP ANTAGONIST AND A BASIC EXCIPIENT

5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. _____

as suggested by the applicant.

as selected by this Authority, because the applicant failed to suggest a figure.

as selected by this Authority, because this figure better characterizes the invention.

b. none of the figures is to be published with the abstract.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

10/551943

Claims Nos.: 1-26 partly

Present independent claim 1 relates to an extremely large number of possible oral dosage forms, namely all those comprising: 1) a reversible PPI ("proton pump antagonist" or APA), and 2) a basic excipient, with no restriction or limitation, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such dosage forms, namely film-coated immediate release tablets comprising soraprazan (as defined in claim 18) and a basic compound as defined in claims 15 and 16. Other possibilities are not sufficiently disclosed in the application. In particular, it is not proved that the stabilising effect is also achieved for other APAs different from soraprazan. The area covered by the claims is broader than justified by the extent of the disclosure. It follows that the claims so lack support, and/or the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. It is the same for independent claims 22 and 23.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the dosage form by reference to the result to be achieved, expressed in terms of parameters (disintegration rate; see claims 3, 6-10 and 23-25), which only amounts to claiming the technical problem to be solved instead of claiming the relevant technical features which amount to its solution. This lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to claim 1 taken in combination with claims 5, 15 and 16, and 18, as interpreted in connection with the description and the examples.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: 1-26 partly because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61K9/20 A61K31/4439 A61K9/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/45693 A (BYK GULDEN LOMBERG CHEM FAB ; LINDEM RUDOLF (DE); NEY HARTMUT (DE); DI) 13 June 2002 (2002-06-13) cited in the application page 44, line 9 - page 46, line 6 examples 27-29 page 40, paragraph 5 page 41, paragraph 2 page 42, paragraph 3 example N -----	1-26
X	DE 199 25 710 A (BYK GULDEN LOMBERG CHEM FAB) 14 December 2000 (2000-12-14) column 3, line 40 - line 63 column 4, line 23 - line 28 column 4, line 60 - line 68 examples column 5, line 18 - line 25 -----	1-16, 22-26
Y	-----	17-21
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

- * Special categories of cited documents :
- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

2 December 2004

Date of mailing of the international search report

10/12/2004

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/74654 A (BYK GULDEN LOMBERG CHEM FAB ; LINDER RUDOLF (DE); DIETRICH RANGO (DE)) 14 December 2000 (2000-12-14) page 6, paragraph 6 – page 7, paragraph 4 examples	1-16, 22-26
Y	-----	17-21
X	US 2002/045646 A1 (PHILLIPS JEFFREY O) 18 April 2002 (2002-04-18) paragraphs '0036!', '0037!', '0085! – '0090!, '0278!, '0394!, '0398! – '0403!, '0418! – '0432!, '0436! – '0446! Tablet D3, example I table 8	1-16, 22-26
Y	-----	17-21
P, X	US 2004/028737 A1 (DESHMUKH SATISH RAMACHANDRA ET AL) 12 February 2004 (2004-02-12) examples 3,4	1-16, 22-26
X	-----	
X	EP 1 222 922 A (EISAI CO LTD) 17 July 2002 (2002-07-17) examples 4-8; table 2	1-16, 22-26
Y	-----	17-21
X	US 6 299 904 B1 (SHIMIZU TOSHIHIRO ET AL) 9 October 2001 (2001-10-09) column 6, line 65 – column 7, line 34' example 5	1-16, 22-26
Y	-----	17-21
X	US 4 786 505 A (ODA MINORU ET AL) 22 November 1988 (1988-11-22) examples 9,10	1-16, 22-26
Y	-----	17-21
X	WO 98/50019 A (CHEN JIVN REN ; SAGE PHARMACEUTICALS INC (US)) 12 November 1998 (1998-11-12) examples	1-16, 22-26
Y	-----	17-21
X	WO 00/78284 A (LAHAV RAFFAEL ; AZOULAY VALERIE (IL); DEXCEL LTD (IL)) 28 December 2000 (2000-12-28) examples 1,4,10,13	1-16, 22-26
Y	-----	17-21

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP2004/050493

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 0245693	A	13-06-2002	AU	1607302 A		18-06-2002
			BR	0115987 A		23-12-2003
			CA	2430828 A1		13-06-2002
			CZ	20031881 A3		14-04-2004
			EE	200300235 A		15-08-2003
			WO	0245693 A1		13-06-2002
			EP	1341527 A1		10-09-2003
			HU	0400566 A2		28-06-2004
			JP	2004514736 T		20-05-2004
			NO	20032593 A		05-08-2003
			US	2004058896 A1		25-03-2004
DE 19925710	A	14-12-2000	DE	19925710 A1		14-12-2000
WO 0074654	A	14-12-2000	AU	775995 B2		19-08-2004
			AU	5074100 A		28-12-2000
			BG	106165 A		30-09-2002
			BR	0011347 A		19-03-2002
			CA	2376202 A1		14-12-2000
			CN	1361683 T		31-07-2002
			CZ	20014405 A3		17-04-2002
			EE	200100660 A		15-04-2003
			WO	0074654 A1		14-12-2000
			EP	1187601 A1		20-03-2002
			HR	20020006 A1		30-04-2003
			HU	0201637 A2		28-11-2002
			JP	2003501377 T		14-01-2003
			MX	PA01012659 A		04-09-2003
			NO	20015980 A		23-01-2002
			PL	352882 A1		22-09-2003
			SK	18022001 A3		04-04-2002
			TR	200103527 T2		22-04-2002
			ZA	200110000 A		03-10-2002
US 2002045646	A1	18-04-2002	US	6489346 B1		03-12-2002
			US	5840737 A		24-11-1998
			BR	0210971 A		24-08-2004
			CA	2453117 A1		06-02-2003
			EP	1414452 A1		06-05-2004
			JP	2004521955 T		22-07-2004
			WO	03009846 A1		06-02-2003
			US	2003191159 A1		09-10-2003
			US	2004048896 A1		11-03-2004
			US	2004171646 A1		02-09-2004
			AU	3276701 A		24-07-2001
			BR	0107565 A		11-02-2003
			CA	2396159 A1		19-07-2001
			EP	1246622 A1		09-10-2002
			EP	1430895 A1		23-06-2004
			JP	2003519656 T		24-06-2003
			MX	PA02006780 A		06-10-2003
			NO	20023313 A		30-08-2002
			PL	357144 A1		12-07-2004
			WO	0151050 A1		19-07-2001
			US	2003118669 A1		26-06-2003
			US	2003144306 A1		31-07-2003
			US	2003215527 A1		20-11-2003
			US	2004058018 A1		25-03-2004

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP2004/050493

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 2002045646	A1	ZA	200205512 A	10-02-2004
		AU	1907100 A	22-05-2000
		WO	0026185 A2	11-05-2000
US 2004028737	A1	12-02-2004	NONE	
EP 1222922	A	17-07-2002	AU 7950200 A CA 2387746 A1 EP 1222922 A1 HU 0203333 A2 NO 20021875 A CN 1382049 T WO 0128559 A1	30-04-2001 26-04-2001 17-07-2002 28-02-2003 04-06-2002 27-11-2002 26-04-2001
US 6299904	B1	09-10-2001	AT 209898 T AU 7451198 A CA 2286753 A1 CN 1130194 B DE 69802810 D1 DE 69802810 T2 EP 0996424 A1 ES 2164424 T3 WO 9853798 A1 JP 11043429 A TW 580397 B US 2001009678 A1	15-12-2001 30-12-1998 03-12-1998 10-12-2003 17-01-2002 18-04-2002 03-05-2000 16-02-2002 03-12-1998 16-02-1999 21-03-2004 26-07-2001
US 4786505	A	22-11-1988	GB 2189698 A SG 154294 G AR 240250 A1 AT 84215 T AT 140387 T AT 184482 T AU 601974 B2 AU 7191287 A CA 1292693 C CN 87103284 A ,B CY 1810 A DD 273197 A5 DE 3751860 D1 DE 3751860 T2 DE 3783394 D1 DE 3783394 T2 DE 247983 T1 DK 215887 A EP 0247983 A2 EP 0496437 A2 EP 0567201 A2 ES 2006457 T3 ES 2091971 T3 ES 2135443 T3 FI 871913 A ,B, GR 89300058 T1 GR 3007434 T3 GR 3020734 T3 GR 3032101 T3 HK 52897 A HK 135294 A	04-11-1987 17-03-1995 30-03-1990 15-01-1993 15-08-1996 15-10-1999 27-09-1990 05-11-1987 03-12-1991 11-11-1987 20-10-1995 08-11-1989 22-08-1996 21-11-1996 18-02-1993 06-05-1993 27-09-1990 31-10-1987 02-12-1987 29-07-1992 27-10-1993 01-01-1994 16-11-1996 01-11-1999 31-10-1987 22-06-1989 30-07-1993 30-11-1996 31-03-2000 02-05-1997 09-12-1994

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP2004/050493

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 4786505	A		HR 920854 A1 HU 43954 A2 IE 61416 B1 JP 1863556 C JP 62258320 A JP 5069807 B JP 2740993 B2 JP 5294831 A KR 9104579 B1 LT 1683 A ,B LV 10357 A ,B LV 5760 A4 NO 871790 A ,B, NZ 220096 A PH 25701 A PL 265416 A1 PT 84785 A ,B SI 8710681 A8 SU 1820837 A3	31-10-1994 28-01-1988 02-11-1994 08-08-1994 10-11-1987 01-10-1993 15-04-1998 09-11-1993 06-07-1991 25-07-1995 20-02-1995 20-12-1996 02-11-1987 26-04-1990 18-09-1991 21-07-1988 01-05-1987 31-10-1996 07-06-1993
WO 9850019	A	12-11-1998	AU 7375598 A JP 2001524131 T TW 550090 B WO 9850019 A1 US 2001006649 A1 US 2003203018 A1	27-11-1998 27-11-2001 01-09-2003 12-11-1998 05-07-2001 30-10-2003
WO 0078284	A	28-12-2000	AU 5423200 A CA 2377605 A1 EP 1187599 A1 WO 0078284 A1	09-01-2001 28-12-2000 20-03-2002 28-12-2000